

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number	10762210
Filing Date	2004-01-20
First Named Inventor	Ronald J. Berenson
Art Unit	1651
Examiner Name	Taeyoon Kim
Attorney Docket Number	980034.417C5

U.S. PATENTS

[Remove](#)

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

[Add](#)

U.S. PATENT APPLICATION PUBLICATIONS

[Remove](#)

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20030064067	A1	2003-04-03	Masuyama	
	2	20030124122	A1	2003-07-03	Berenson et al.	
	3	20040005298	A1	2004-01-08	Bonyhadi et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button.

[Add](#)

FOREIGN PATENT DOCUMENTS

[Remove](#)

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	0953351	EP	A2	1999-11-03	Sekine et al.		<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10762210
Filing Date	2004-01-20
First Named Inventor	Ronald J. Berenson
Art Unit	1651
Examiner Name	Taeyoon Kim
Attorney Docket Number	980034.417C5

2	0189539	WO	A2	2001-11-29	Xcyte Therapies, Inc.	<input type="checkbox"/>
3	1211311	EP	A2	2002-06-05	Humantec Ltd. et al.	<input type="checkbox"/>
4	1241249	EP	A1	2002-09-18	Gerold Schuler	<input type="checkbox"/>
5	03038062	WO	A2	2003-05-08	The Government of the United States of America	<input type="checkbox"/>
6	03067221	WO	A2	2003-08-14	Xcyte Therapies, Inc.	<input type="checkbox"/>
7	2004003142	WO	A2	2004-01-08	Xcyte Therapies, Inc.	<input type="checkbox"/>
8	1391210	EP	A2	2004-02-25	Gerold Schuler	<input type="checkbox"/>
9	2005030251	WO	A1	2005-04-07	Xcyte Therapies, Inc.	<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

Add

NON-PATENT LITERATURE DOCUMENTS

Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	BARTLETT et al., "A Phase II Study of Xcellerated T Cells™ in Patients with Relapsed or Refractory Indolent Non-Hodgkin's Lymphoma (NHL)," Blood (ASH Annual Meeting Abstracts), 104: Abstract 4640, 2004.	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		10762210
Filing Date		2004-01-20
First Named Inventor	Ronald J. Berenson	
Art Unit	1651	
Examiner Name	Taeyoon Kim	
Attorney Docket Number	980034.417C5	

2	BAUER et al., "Large Scale Ex Vivo GMP Expanded, Activated Human T Cells Consistently Induce Lethal GvHD in a Mouse Xenotransplant Model-A New Way To Study Treatments for Acute GvHD," Blood (ASH Annual Meeting Abstracts), 106: Abstract 5242, 2005.	<input type="checkbox"/>
3	BERENSON et al., "Xcellerate™ Therapy: A Novel Therapeutic Strategy for the Treatment of Autoimmune Diseases," Blood (ASH Annual Meeting Abstracts), 102: Abstract 839, November 16, 2003.	<input type="checkbox"/>
4	BERENSON et al., "A Randomized Phase II Study of Xcellerated T Cells™ with or without Prior Fludarabine Therapy in Patients with Relapsed or Refractory Multiple Myeloma," Blood (ASH Annual Meeting Abstracts), 104: Abstract 2410, 2004.	<input type="checkbox"/>
5	BERENSON et al., "Combined Cyto reduction and Infusion of Anti-CD3/Anti-CD28 Bead-Activated T Cells Prevent Diabetes in NOD Mice," Blood (ASH Annual Meeting Abstracts), 106: Abstract 3036, 2005.	<input type="checkbox"/>
6	BERENSON et al., "Anti-CD3/Anti-CD28 Bead-Activated T Cells Facilitate Engraftment of Murine Histoincompatible Allogeneic Transplants after Low-Dose Radiation," Blood (ASH Annual Meeting Abstracts), 106: Abstract 5221, 2005.	<input type="checkbox"/>
7	BERGER et al., "CD28 costimulation and immunoaffinity-based selection efficiently generate primary gene-modified T cells for adoptive immunotherapy," Blood, 101(2):476-484, January 15, 2003.	<input type="checkbox"/>
8	BONDANZA et al., "Suicide Gene Therapy of Graft-Versus-Host Disease Induced by Central Memory Human T Lymphocytes," Blood (ASH Annual Meeting Abstracts), 106: Abstract 3096, 2005.	<input type="checkbox"/>
9	BONDANZA et al., "Suicide gene therapy of graft-versus-host disease induced by central memory human T lymphocytes," Blood, 107:1828-1836, 2006.	<input type="checkbox"/>
10	BONYHADJ et al., "In Vitro Engagement of CD3 and CD28 Corrects T Cell Defects in Chronic Lymphocytic Leukemia," J. Immunol., 174:2366-2375, 2005.	<input type="checkbox"/>
11	BORRELLO et al., "A Phase I/II study of Xcellerated T Cells after autologous peripheral blood stem cell transplantation in patients with multiple myeloma," ASCO Annual Meeting Proceedings (Post-Meeting Edition) 22(14S): 2540, July 15, 2004.	<input type="checkbox"/>
12	CARROLL et al., "Differential Regulation of HIV-1 Fusion Cofactor Expression by CD28 Costimulation of CD4 + T Cells," Science, 276:273-276, April 11, 1997.	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10762210
Filing Date	2004-01-20
First Named Inventor	Ronald J. Berenson
Art Unit	1651
Examiner Name	Taeyoon Kim
Attorney Docket Number	980034.417C5

13	CASTRO et al., "A Phase I/II Trial of Xcellerated T Cells™ in Patients with Chronic Lymphocytic Leukemia," Blood (ASH Annual Meeting Abstracts), 104: Abstract 2508, 2004.	<input type="checkbox"/>
14	COITO et al., "Retrovirus-Mediated Gene Transfer in Human Primary T Lymphocytes Includes an Activation- and Transduction/Selection-Dependent TCR-B Variable Chain Repertoire Skewing of Gene-Modified Cells," Stem Cells and Development, 13:74-81, 2004.	<input type="checkbox"/>
15	DANG et al., "Tumor Antigen-Specific T-Cell Expansion Is Greatly Facilitated by In vivo Priming," Clin. Cancer Res., 13(6):1883-1891, March 15, 2007.	<input type="checkbox"/>
16	DEEKS et al., "A Phase II Randomized Study of HIV-Specific T-Cell Gene Therapy in Subjects with Undetectable Plasma Viremia on Combination Antiretroviral Therapy," Molecular Therapy, 5(6):788-797, June 2002.	<input type="checkbox"/>
17	EARLE et al., "In vitro expanded human CD4+CD25+ regulatory T cells suppress effector T cell proliferation," Clin. Immunol., 115:3-9, 2005.	<input type="checkbox"/>
18	FERRAND et al., "Retrovirus-Mediated Gene Transfer in Primary T Lymphocytes: Influence of the Transduction/ Selection Process and of ex Vivo Expansion on the T Cell Receptor β Chain Hypervariable Region Repertoire," Human Gene Therapy, 11:1151-1164, May 20, 2000.	<input type="checkbox"/>
19	FOWLER et al., "Phase I clinical trial of donor T-helper Type-2 cells after immunoablative, reduced intensity allogeneic PBSC transplant," Cytotherapy, 4(5):429-430, 2002.	<input type="checkbox"/>
20	GARLIE et al., "T Cells Coactivated with Immobilized Anti-CD3 and Anti-CD28 as Potential Immunotherapy for Cancer," J. Immunotherapy, 22(4):336-345, 1999.	<input type="checkbox"/>
21	GLODE et al., "A phase I/II trial of CD3/CD28 activated T cells (Xcellerated T Cells) in patients with hormone refractory prostate cancer," ASCO Annual Meeting Proceedings (Post-Meeting Edition), 22(14S):2549, July 15, 2004.	<input type="checkbox"/>
22	GODFREY et al., "In vitro-expanded human CD4+CD25+ T-regulatory cells can markedly inhibit allogeneic dendritic cell-stimulated MLR cultures," Blood, 104:453-461, March 18, 2004.	<input type="checkbox"/>
23	GODFREY et al., "Cord blood CD4+CD25+-derived T regulatory cell lines express FoxP3 protein and manifest potent suppressor function," 105:750-758, September 16, 2004.	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10762210
Filing Date	2004-01-20
First Named Inventor	Ronald J. Berenson
Art Unit	1651
Examiner Name	Taeyoon Kim
Attorney Docket Number	980034.417C5

24	GREEN et al., "A Four-Color Flow Cytometry-Based Assay for Detection of Residual Leukemic B Cells in Xcellerated T Cells™ for Infusion into CLL Patients," Blood (ASH Annual Meeting Abstracts), 102(11): Abstract 5426, 2003.	<input type="checkbox"/>
25	GRIBBEN et al., "A Phase II Study of Xcellerated T Cells TM in Patients with Relapsed or Refractory Indolent Non-Hodgkin's Lymphoma (NHL)," ASCO Annual Meeting Proceedings, 23(16S):2510, June 1, 2005.	<input type="checkbox"/>
26	HAMI et al., "Comparison of a Static Process and a Bioreactor-based Process for the GMP Manufacture of Autologous Xcellerated T Cells for Clinical Trials," BioProcessing, 2(6):1-10, November/December 2003.	<input type="checkbox"/>
27	HAMI et al., "Comparability of Xcellerated T Cells™ Manufactured Using a Static Culture Process and a Bioreactor Process for the Treatment of Patients with Multiple Myeloma," Blood (ASH Annual Meeting Abstracts), 102(11): Abstract 3592, 2003.	<input type="checkbox"/>
28	HAMI et al., "Reproducibility and Robustness of the Xcellerate III Process for the GMP Manufacture of Xcellerated T Cells™ for Infusion into CLL Patients," Blood (ASH Annual Meeting Abstracts), 104: Abstract 4995, 2004.	<input type="checkbox"/>
29	HAMI et al., "GMP production and testing of Xcellerated T Cells™ for the treatment of patients with CLL," Cytotherapy, 6(6):554-562, 2004.	<input type="checkbox"/>
30	HUMEAU et al., "Efficient Lentiviral Vector-Mediated Control of HIV-1 Replication in CD4 Lymphocytes from Diverse HIV+ Infected Patients Grouped According to CD4 Count and Viral Load," Molecular Therapy, 9(6):902-913, June 2004.	<input type="checkbox"/>
31	KALAMASZ et al., "Optimization of Human T-Cell Expansion Ex Vivo Using Magnetic Beads Conjugated with Anti-CD3 and Anti-CD28 Antibodies," J. Immunother., 27(5):405-418, September/October 2004.	<input type="checkbox"/>
32	KARAKHANOVA et al., "Highly Efficient Expansion of Human CD4+CD25+ Regulatory T Cells for Cellular Immunotherapy in Patients with Graft-Versus-Host Disease," J. Immunother., 29(3):336-349, May/June 2006.	<input type="checkbox"/>
33	KEEVER-TAYLOR et al., "Rapamycin enriches for CD4+CD25+CD27+ Foxp3+ regulatory T cells in ex vivo-expanded CD25-enriched products from healthy donors and patients with multiple sclerosis," Cytotherapy, 9(2):144-157, 2007.	<input type="checkbox"/>
34	KIPPS et al., "A Phase I/II Trial of Xcellerated T Cells™ in Patients with Chronic Lymphocytic Leukemia (CLL)," Blood (ASH Annual Meeting Abstracts), 102(11): Abstract 370, 2003.	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10762210
Filing Date	2004-01-20
First Named Inventor	Ronald J. Berenson
Art Unit	1651
Examiner Name	Taeyoon Kim
Attorney Docket Number	980034.417C5

35	KIPPS et al., "A Phase I/II Study of Xcellerated T Cells TM in Patients with Chronic Lymphocytic Leukemia," ASCO Annual Meeting Proceedings, 23(16S):2511, June 1, 2005.	<input type="checkbox"/>
36	LAPORT et al., "Adoptive transfer of costimulated T cells induces lymphocytosis in patients with relapsed/refractory non-Hodgkin lymphoma following CD34+-selected hematopoietic cell transplantation," Blood, 102(6):2004-2013, September 15, 2003.	<input type="checkbox"/>
37	LEVINE et al., "Antiviral Effect and Ex Vivo CD4+ T Cell Proliferation in HIV-Positive Patients as a Result of CD28 Costimulation," Science, 272:1939-1943, June 28, 1996.	<input type="checkbox"/>
38	LEVINE et al., "Effects of CD28 Costimulation on Long-Term Proliferation of CD4+ T Cells in the Absence of Exogenous Feeder Cells," J. Immunol., 159:5921-5930, 1997.	<input type="checkbox"/>
39	LEVINE et al., "Large-Scale Production of CD4+ T Cells from HIV-1-Infected Donors After CD3/CD28 Costimulation," J. Hematother., 7:437-448, 1998.	<input type="checkbox"/>
40	LEVINE et al., "Adoptive transfer of costimulated CD4+ T cells induces expansion of peripheral T cells and decreased CCR5 expression in HIV infection," Nature Medicine, 8(1):47-53, January 2002.	<input type="checkbox"/>
41	LI et al., "CD4+CD25+ regulatory T-cell lines from human cord blood have functional and molecular properties of T-cell anergy," Blood, 106:3068-3073, July 14, 2005.	<input type="checkbox"/>
42	LONG et al., "Restoring a Normal T Cell Receptor Repertoire Using the Xcellerate™ Technology: A Potential Therapeutic Strategy for Patients with Hematological Disorders and Autoimmune Diseases," Blood (ASH Annual Meeting Abstracts), 104: Abstract 3853, 2004.	<input type="checkbox"/>
43	LONG et al., "Activated and Expanded T Cells for Potential Therapy of Patients with Autoimmune Diseases," Blood (ASH Annual Meeting Abstracts), 104: Abstract 3854, 2004.	<input type="checkbox"/>
44	LUM et al., "Immune Modulation in Cancer Patients After Adoptive Transfer of Anti-CD3/Anti-CD28-Costimulated T Cells--Phase I Clinical Trial," J. Immunol., 24(5):408-419, 2001.	<input type="checkbox"/>
45	MITSUYASU et al., "Prolonged survival and tissue trafficking following adoptive transfer of CD4ζ gene-modified autologous CD4+ and CD8+ T cells in human immunodeficiency virus-infected subjects," Blood, 96(3):785-793, August 1, 2000.	<input type="checkbox"/>

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10762210
Filing Date	2004-01-20
First Named Inventor	Ronald J. Berenson
Art Unit	1651
Examiner Name	Taeyoon Kim
Attorney Docket Number	980034.417C5

46	NERVI et al., "In Vivo Suicide Gene Therapy of Human T Lymphocytes To Prevent Graft Versus Host Disease in a Murine Xenograft Model," Blood (ASH Annual Meeting Abstracts), 104: Abstract 4979, 2004.	<input type="checkbox"/>
47	NERVI et al., "Naive and Ex Vivo Activated Human T Cells Generate Consistent Engraftment and Lethal Graft-Versus-Host Disease (GvHD) in NOD SCID β 2M Null Mice: A New Xenogeneic Model for GvHD," Blood (ASH Annual Meeting Abstracts), 105: Abstract 3106, 2005.	<input type="checkbox"/>
48	NOONAN et al., "Activated Marrow-Infiltrating Lymphocytes Effectively Target Plasma Cells and Their Clonogenic Precursors," Cancer Res., 65(5):2026-2034, March 1, 2005.	<input type="checkbox"/>
49	NOONAN et al., "CD4+CD25+ Marrow Infiltrating Lymphocytes in Myeloma Patients Display an Activated Phenotype and Lack Suppressive Function," Blood (ASH Annual Meeting Abstracts), 108: Abstract 1741, 2006.	<input type="checkbox"/>
50	ONLAMOON et al., "Optimization of in vitro expansion of macaque CD4+ T cells using anti-CD3 and co-stimulation for autotransfusion therapy," J. Med. Primatol. 35:178-193, 2006.	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.